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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,657	04/16/2001	Nathalie Garcon	B 45158	2235

7590 10/19/2005

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,657

Applicant(s)

GARCON, NATHALIE

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) 32-37, 73, 74, 76, 79-81, 84, 85, 95, 96, 106, 107, 109, 115 and 135-141 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/28 & 9/29 2005</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 32-37,39-42,46,48-53,56,58-62,71,73-82,84-86,88-93,95-97,99-104,106-116,120-125,127,131 and 133-141.

Continuation of Disposition of Claims: Claims allowed are 39-42,46,48-53,56,58-62,71,75,77,78,82,86,88-93,97,99-104,108,110-114,116,120-125,127,131,133 and 134.

DETAILED ACTION

Status of the Claims

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submissions filed on July 26, and September 23, 2005 have been entered.

2. Claims 32-37, 39-42, 44-46, 48-53, 55, 56, 58-62, 71, 73-82, 84-86, 88-93, 95-97, 99-104, 106-116, 120-125, 127, 129-131, and 133-141 were pending and allowed in the prior action. In the prior action, the Ex parte Quayle action mailed on January 26, 2005, claims 32-37, 39-62, 71-116, and 118-141 were indicated to be allowable, and the specification was objected to. In an amendment accompanying the RCE of March 24, 2005, the Applicant amended claims 32-37, 39-42, 44-46, 48-53, 55, 56, 58--62, 71, 73-82, 84-86, 88-93, 95-97, 99-104, 106-114, 116, 120-124, 127, 129-131, and 133-137; and cancelled claims 43, 47, 54, 57, 72, 83, 87, 94, 98, 105, 118, 119, 126, 128, and 132. Because the amendments to the claims have rendered moot the outstanding objection to the specification, and in view of the amendments below, the application is considered to be in allowable condition.

In addition, the Response of September 23, 2005 additionally cancelled claims 44, 45, 55, 129, and 130.

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Thus, claims 32-37, 39-42, 46, 48-53, 56, 58-62, 71, 73-82, 84-86, 88-93, 95-97, 99-104, 106-116, 120-125, 127, 131, and 133-141 are pending.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on July 28 and on September 29 2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

However, it is noted that certain of the cited references have been crossed out and not considered.

In the July 2005 IDS:

Application 10/070,479 was previously made of record in the March 2005 IDS.

U.S. Patent 5,776,468 was previously made of record Office action of September 2002.

WO 1996/26741 was previously cited (as WO 96/26741) in the April 2001 IDS.

In the September 2005 IDS:

U.S. 5,776,468, WO 93/019780, and WO 94/21292 were previously made of record in the July 2005 IDS.

These references have therefore been crossed off of the present information disclosure statements because the references have already been made of record and considered.

4. The following reference is in a foreign language, and is accompanied by an English abstract/claims. Due to this, the reference has been considered only to the extent of the disclosure in English.

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EP 0 008 728.

Allowable Subject Matter

5. Claims 39-42, 44-46, 48-53, 55, 56, 58-62, 71, 75, 77, 78, 82, 86, 88-93, 97, 99-104, 108, 110-116, 120-125, 127, 129-131, 133, and 134 are allowed. The subject matter of these claims appears to be free of the prior art. Although the art does teach the combination of the claimed immunostimulants and adjuvants, (see e.g. Hauser et al., U.S. Patent 5,776,468, col. 7, lines 27-39 (of record in the prior action), the art does not specifically teach adjuvant compositions wherein the antigen and immunostimulant are not bound to the same adjuvant molecules. See e.g., Hauser, col. 1, lines 45-53 (teaching that the immunostimulant reacts with the alum/antigen complex to form a single complex comprising all three elements). In particular, it is noted that the teachings of the Hauser patent indicated that alum bound antigens will also react with (complex with) additional immunostimulants added to the compositions. See e.g., Hauser, column 1 (supra), and the discussion in paragraph 15 of the Office Action mailed in March 2003. While the Applicant teaches that methods of manipulating the components such that the claimed compositions are achieved could have been carried out by those in the art (pages 18-20 of the Response filed in June 2003), there does not appear to be any motivation or suggestion in the art that such manipulations should actually be carried out. For these reasons, and the reasons of record, the pending claims are found allowable.

Specification

6. The specification is objected to for containing referring to sequences without also identifying them by the sequence identifier assigned to them in the sequence listing as required

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by 37 CFR 1.821(d). See e.g., p. 6, lines 30-32. The examiner would like to bring the applicant's attention to the following excerpt from MPEP §2422.03:

37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

The applicant is therefore required to amend the specification to comply with 37 CFR 1.821(d).

Claim Objections

7. **(New Objection)** Claim 140 is objected to because of the following informalities: the claim refers to polynucleotide sequences without also referring to them by the appropriate SEQ ID NOs as required under 37 CFR 1.821(d). Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **(New Rejection- Necessitated by Amendment)** Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims each

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depend, directly or indirectly, from canceled claims 44, 45, 55, 129, and 130. In view of this, it is not clear what is being further limited. The claims are therefore indefinite.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. **(New Rejection- Based on art cited in IDS)** Claims 32-37, 115, 138, and 139 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 576 478 (of record in the September 29, 2005 IDS). These claims are drawn to adjuvant compositions comprising an immunostimulant (including 3D-MPL) adsorbed to a metallic salt, wherein the adjuvant is substantially free of adjuvant. Claim 115 is drawn to kits comprising the adjuvant composition in one container and an antigen in another. The reference teaches the claimed adjuvant compositions. Pages 3-4 (teaching the making of the adjuvant formulations, and the administration of such without antigen). The reference further teaches compositions both with and without the antigen, indicating that the antigen is kept in a separate container initially, and then added when necessary to the adjuvant. Id. The reference therefore anticipates the indicated claims.

Claim Rejections - 35 USC § 103

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12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **(New Rejection- Based on art cited in IDS)** Claims 138-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 576 478 as applied to claims 32-37, 115, 138, and 139 above, and further in view of the Applicant's admission on pages 1, 5-6 of the application that vaccine compositions comprising the indicated immunostimulants were known in the art and of the Vogel et al. reference cited in the September 2005 IDS. These claims describe adjuvant compositions as described above wherein other immunostimulants than 3d-MPL are adsorbed to the metallic salt. EP 0 576 478 illustrates that it is obvious to those in the art to make adjuvant compositions to which antigens will later be added. See e.g., page 3-4 (teaching the making of the adjuvant compositions, and teachings the administration of such compositions without adjuvant, thereby indicating that they were made separately from the antigen until the antigen is added). However, the teachings of the reference disclose only adjuvants comprising 3d-MPL adsorbed to alum. Nonetheless, in view of the recognition in the application that the other indicated immunostimulants were known in the art and the teachings in the Vogel reference of several of these adjuvants (see e.g., pages 142, 151, 152, 154, 156 and 166) it would have been obvious to those in the art to first make the adjuvant compositions and then, later, to add the antigens. Thus, the teachings of the EP reference in combination with what the Applicant admits

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was known in the art would have rendered obvious the claimed adjuvant compositions to those of ordinary skill in the art.

Conclusion

14. The following prior art references are made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

U.S. 5,773,011. This reference teaches that zinc produces an adjuvant effect. Col. 4, lines 11-15.

U.S. 5,698,679. This reference teaches that aluminum and calcium salts are useful adjuvants. Column 21, lines 40-52.

U.S. 5,252,327. This reference teaches iron and zinc salts useful as adjuvants. Abstract. Wedrychowicz et al., Int J Parasitol 25: 1111-21. This reference teaches the use of a beryllium salt as an adjuvant.

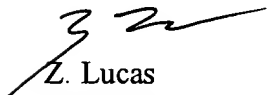
These references provide examples illustrating that, as indicated on page 1 of the application, metallic salts are known in the art as useful adjuvants. Based on the admission of what was known in the prior art, and on these references, it would therefore have been obvious to use the metals identified on page 1 of the application in adjuvant compositions as indicated by EP 0 576 478.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


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